IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE BRIMONIDINE PATENT LITIGATION	))	C.A. No. 07-md-1866-GMS

JOINT STATUS REPORT

DATED: February 1, 2008

Pursuant to the Court's November 15, 2007, Order Setting Scheduling Conference ("Order") the parties hereby submit the following Joint Status Report which addresses each item set forth in paragraph 3(b) of that Order.

1. **Jurisdiction and Service.** *Does the court have subject matter jurisdiction? Are all parties subject to the court's jurisdiction? Do any remain to be served?*

This Court has jurisdiction to conduct coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407 and pursuant to an order of the Judicial Panel on Multidistrict Litigation (MDL Dkt. No. 2). This Multidistrict Litigation comprises two actions, *Allergan, Inc. v. Exela PharmSci, Inc. et al*., No. 07-1967 (C.D. Cal. filed Mar. 6, 2007) (the "California Action"); and *Allergan, Inc. v. Apotex, Inc. & Apotex Corp.*, No. 07-278 (D. Del. filed May 5, 2007) (the "Delaware Action").

All claims and counterclaims arise under the U.S. Patent laws alone or in conjunction with the provisions for Declaratory Judgments. Accordingly, this Court has subject matter jurisdiction in accordance with 28 U.S.C. §§ 1331, 1338 and 2201. All parties have been served.

2. **Substance of the Action.** *What are the factual and legal bases for plaintiff's claims and defendants' defenses?*

Allergan: This is the consolidation of two actions brought by Allergan, one in California and one in Delaware, under the Hatch-Waxman act for patent infringement by two different groups of defendants' proposed generic brimonidine products. Brimonidine is used in the treatment of glaucoma, the sight-depriving disease that affects millions of Americans annually. Allergan sells two different strengths of brimonidine solutions (0.15% and 0.1%) under the trade-name ALPHAGAN P.

These cases were consolidated in this Court for the reasons set forth in the MDL panel's order, one of which is this Court's previous experience with the technology at issue in *Allergan,*

Inc. v. Alcon Inc., Civil Action No. 04-968-GMS. The cases concern the following U.S. Patents, all owned by Allergan: U.S. 5,424,078; U.S. 6,562,873; U.S. 6,627,210; U.S. 6,673,337; and U.S. 6,641,834.

The California Defendants submitted an Abbreviated New Drug Application (No. 78-590) to the FDA for approval to make, use and sell generic brimonidine tartrate ophthalmic solution 0.15%. The Delaware Defendants submitted two Abbreviated New Drug Applications (Nos. 78-479 and 78-480) to the FDA for FDA approval of 0.15% and 0.10% brimonidine tartrate ophthalmic solutions.

Allergan has alleged infringement of each of the five patents against both the Delaware Defendants and the California Defendants. With respect to the California Defendants' comments below on the relevant patents to the dispute over their proposed generic version of ALPHAGAN P 0.15%, at this juncture Allergan confirms that it is currently asserting all five patents against the California Defendants. While the issues may be narrowed against the California Defendants, Allergan is not in a position to do so at the present time. This is the case because the California Defendants' paragraph IV letter, while filled with lengthy legal argument, contained almost no information about their proposed generic product, thereby making it impossible to assess infringement as to the five asserted patents from the letter, as the Hatch-Waxman Act contemplates. For example, unlike the Apotex paragraph IV letter, the complete formulation of the proposed generic product was not provided in the California Defendants' paragraph IV letter. When Allergan asked for additional information about the formulation and copies of the ANDA, the parties could not agree on suitable confidentiality terms for the provision of that information, including the conditions under which in-house counsel responsible for this action might be provided that information. With only the information contained in the paragraph IV certification

in hand, Allergan initially brought suit against the California Defendants only on the '834 patent, for which there was sufficient information to establish infringement in defendants' paragraph IV certification. After the California Defendants filed a declaratory judgment action on the remaining four patents (originally in the Eastern District of Virginia, but then later in the Central District of California), Allergan was required to counterclaim on those patents as a matter of procedural law. Allergan's precautionary counterclaim was brought pursuant to *Hoffman-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359 (Fed. Cir. 2000), which permits such claims until such time as further information could be ascertained regarding the California Defendants' proposed generic products.

After consolidation and transfer of the California action to this Court, the California Defendants produced their ANDA, but only pursuant to Delaware Local Rule 26.2, which permits access only to counsel who have appeared in this action. Accordingly, Allergan's outside counsel has been unable to discuss the California Defendants' ANDA with either its client or its retained experts for this case. Once a protective order has been entered and Allergan's outside counsel is able to share the ANDA with an expert, take any necessary discovery, and advise its client, Allergan will notify the California Defendants of which claims of which patents it is asserting.

The California Defendants: This patent infringement case arises under the Hatch-Waxman Act. Allergan filed the California Action after Exela filed an ANDA seeking FDA approval to market its 0.15% brimonidine tartarate ophthalmic solution. Specifically, Exela sent Allergan a statutory notice letter required under the Hatch-Waxman Act informing Allergan of Exela's ANDA filing, and setting forth a detailed statement of the factual and legal bases for Exela's assertions that: (1) Exela's proposed product did not infringe any of the five patents

listed in FDA's *Orange Book* for Allergan's product, and (2) those patents are invalid. After receiving Exela's notice letter, Allergan sued Exela (later amended to include all of the California Defendants) alleging infringement of only one of the *Orange Book* patents—the '834 patent. The California Defendants filed counterclaims seeking a declaratory judgment of noninfringement and invalidity as to each of the five *Orange Book* patents. In response to those counterclaims, Allergan filed counterclaims on reply asserting infringement of the remaining four *Orange Book* patents. Allergan characterized its infringement assertions of the four *Orange Book* patents as "precautionary" in filings with the California district court. The California Defendants assert that they do not infringe any of the asserted patents because, among other things, the Exela ANDA product uses a prior-art formulation that is not covered by any of the claims of the patents in suit. The California Defendants further assert that all of the asserted patent claims are invalid over the prior art.

Apotex: Allergan is incorrect when it states that the "Delaware Defendants" submitted Abbreviated New Drug Applications Nos. 78-479 and 78-480 to the FDA. Apotex Inc. (a Canadian corporation) is the entity that submitted the Abbreviated New Drug Applications and is named as the applicant. Apotex Corp. (a U.S. corporation) is only identified as the U.S. agent of Apotex Inc. for purposes of dealing with the FDA on the Abbreviated New Drug Applications filed by Apotex Inc.

Apotex Inc. and Apotex Corp. allege that the '078, '873, '210, '337 and '834 patents are invalid in view of the prior art and the failure to meet the written description requirements of the Patent Act. Apotex Inc. and Apotex Corp. also allege that the '078, '210, '834 and '337 patents are unenforceable due to inequitable conduct. Apotex Inc. and Apotex Corp. also allege that the above patents will not be infringed by the manufacture, use, or sale of the proposed products for

which ANDA applications 78-479 and 78-480 were submitted.

3. **Identification of Issues.** *What factual and legal issues are genuinely in dispute?*

Allergan: The disputed issues in this case include the factual and legal issues of patent infringement, validity, and enforceability for all five patents. All of the defendants have raised claims of invalidity for each of the five patents, and have made varying claims of non-infringement of the five patents. Apotex has raised issues of unenforceability as well.

The Delaware Defendants: The disputed issues in this case include the factual and legal issues of patent infringement, validity, and enforceability.

The California Defendants: The California Defendants believe that Allergan will ultimately assert infringement of only the '834 patent against the Exela ANDA product. Allergan characterized its infringement allegations based on the remaining patents as "precautionary," pending receipt of Exela's ANDA. The California Defendants produced the Exela ANDA to Allergan on October 19, 2007, and expect that Allergan should agree to withdraw the remaining patents from the case. At the meet and confer among the parties on January 11, 2007, the California Defendants asked Allergan to identify which claims of which patents it would be asserting in the action. Allergan has refused this request. The California Defendants believe that the noninfringement issues surrounding the '834 patent are narrow and susceptible to resolution on summary judgment. The California Defendants further assert that the claims of the '834 patent are invalid.

4. **Narrowing of Issues.** *Can the issues in litigation be narrowed by agreement or by motions? Are there dispositive or partially dispositive issues appropriate for decision on motion?*

Allergan and Apotex: At this point in the case there has been no substantive discovery. Though there are likely to be common partially dispositive issues that can be resolved through motion practice, they have not yet been identified given the stage of the proceedings.

California Defendants: As discussed above, the California Defendants believe that Allergan should agree to limit the Exela Action to the '834 patent, and to withdraw the remaining patents from the case.

5. **Relief.** *What specific relief does plaintiff seek? What is the amount of damages sought and generally how is it computed?*

Allergan: This is not a damages case, as it currently stands. Allergan seeks an adjudication that the patents-in-suit are infringed by both the California Defendants' and Delaware Defendants' proposed generic brimonidine products, that the patents in suit are not invalid or unenforceable, and that the Court issue an appropriate permanent injunction. Allergan also requests that the Court award such other and further relief as it may deem just and proper.

Defendants: At this stage in the proceedings, the defendants agree that there can be no damages claim by Allergan. However, a claim for damages could arise if either the Apotex Action or the Exela Action is not resolved before expiration of the 30-month stay of approval at the FDA and there is no injunction in force.

6. **Amendment of Pleadings?**

The parties do not anticipate that any amendment of the pleadings is necessary at the present time and have agreed to an amendment deadline of February 29, 2008.

7. **Joinder of Parties?**

The parties do not anticipate the joinder of any additional parties at the present time. If there are additional applications for generic brimonidine products that result in a lawsuit by Allergan, such actions may be joined to this one.

8. **Discovery.** *Discovery contemplated by each party and the amount of time it may take to complete discovery? Can discovery be limited? Are less costly and time-consuming methods available to obtain necessary information? Have the parties explored and discussed the possibility of utilizing a magistrate judge during the discovery process?*

The parties have met and conferred regarding proposed schedules and potential limitations on discovery. The results of the parties' discussions regarding the schedule are contained in the table attached hereto. Allergan requests approximately 10 months from the date discovery resumes to conclude fact and expert discovery against the two groups of defendants.

In addition to meeting and conferring on scheduling, the parties have met and conferred regarding the discovery limitations and devices they intend to use and have been unable to reach agreement on those limitations and devices. They propose the following respective positions on those discovery devices.

Interrogatories:

Allergan: Allergan may propound up to 25 interrogatories directed to the California Defendants and up to 25 interrogatories directed to the Delaware Defendants. The Defendants would share 10 interrogatories and be able to separately propound 15 interrogatories each.

Defendants: Allergan, the California Defendants and the Delaware Defendants would each be entitled to propound up to 25 interrogatories.

Requests for Admission:

Allergan: The California and Delaware Defendants should share 10 joint requests for admission and each would have 10 additional requests for admission to use individually. Allergan would be able to propound 30 requests for admission.

Defendants: Consistent with Federal and Local Rules, there should be no limit on the number of requests for admission.

Depositions:

Allergan: Allergan would be entitled to 75 hours of deposition time for use with the California Defendants and an additional 75 hours of deposition time for use with the Delaware Defendants. The Defendants would share a total of 105 hours of deposition time.

Defendants: Allergan would be entitled to 75 hours of deposition time for use with the California Defendants and an additional 75 hours of deposition time for use with the Delaware Defendants. The California and Delaware Defendants would share 150 hours of deposition time for use with Allergan.

Documents:

The parties are negotiating the process and form for production of Electronically Stored Information, and substantial progress has been made. Accordingly, it is believed that the Default Standard for Discovery of Electronic Documents will not need to be implemented.

Magistrate Judge

Allergan and the Delaware Defendants: Allergan believes that the Court, having previously handled litigation regarding Allergan's brimonidine products and patents, is in the best position to resolve any discovery disputes pursuant to the Court's standard procedures.

The California Defendants: The California Defendants leave to the Court's discretion whether a Magistrate Judge would be appropriate to oversee discovery in this case.

9. **Estimated Trial Length.** *Is it feasible or desirable to bifurcate issues for trial? Is it possible to reduce the length of the trial by stipulations, use of summaries or statements, or other expedited means of presenting evidence?*

Allergan: Allergan estimates that trial of the case against the Delaware defendants will require six Court days. Because there are no damages or claims for willfulness, there is no need

for bifurcation. As to the California defendants, if trial is held in Delaware, Allergan anticipates, at this juncture, six Court days for that trial.

The California Defendants: The California Defendants believe that if the Exela Action is limited to the '834 patent, trial should take 2-3 days. In the event that additional patents are involved and are not disposed of on summary judgment, the California Defendants believe that trial of the Exela Action may take up to 5 days.

Apotex: In view of the five patents at issue, the Apotex Parties estimate that trial of the Apotex Action will take 8 days

10. **Jury Trial?**

While all of the parties have requested a jury trial in order to preserve their rights, in the cases' current postures, no such right exists under current authority. That being said, should some issue arise for which a right to a jury trial exists, the parties will demand a jury trial at that time.

11. **Settlement.** *Have there been settlement discussions? What are the prospects for settlement? Is referral to the Magistrate for mediation or other ADR mechanism appropriate?*

The parties have not engaged in meaningful settlement discussions. While the parties believe the possibility of settlement is small, the parties are open to discuss the issue in the proper situation. Nonetheless, the parties do not believe mediation or other ADR mechanisms are appropriate.

12. **Related cases.** *Are there any related cases pending in federal or state court?*

There are no other currently pending related cases.

13. **Pending Motions.** *Counsel's Joint Status Report shall list all pending motions.*

There are no pending motions from the underlying action from the United States District Court for the District of Delaware.

Allergan and the California Defendants briefed before the United States District Court for the Central District of California the proper scope of a protective order to be entered in this case. The matter was transferred before the Court heard or ruled on that motion. Because the Delaware defendants were not a party to that motion, Allergan suggests that the Court need not resolve it.

Since that motion, the parties have discussed the proper scope of a protective order for this case but have been unable to reach agreement. A dispute remains as to whether Allergan can discuss the Defendants' ANDAs with the FDA and whether in-house counsel can have access to the California Defendants' ANDA, and if so, under what conditions. The parties request the Court's assistance in resolving this dispute and seek the Court's guidance as to the manner in which the Court would like the issues presented.

14. *Such other matters as counsel considers conducive to the just, speedy and inexpensive determination of this action.*

15. *A statement that counsel for the parties have conferred about each of the above matters.*

Counsel for the parties have conferred about each of the matters above.

Dated: February 1, 2008

By: */s/ William J. Marsden, Jr.*

William J. Marsden, Jr. (#2247)
FISH & RICHARDSON P.C.
919 N. Market Street, Suite 1100
P.O. Box 1114
Wilmington, DE 19899-1114
Telephone: (302) 652-5070
Facsimile: (302) 652-0607
Email: marsden@fr.com

Of Counsel:

Jonathan E. Singer
Michael J. Kane
Deanna J. Reichel
FISH & RICHARDSON P.C.
60 South Sixth Street, Suite 3300
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696
Email: singer@fr.com
Email: kane@fr.com
Email: reichel@fr.com

Juanita Brooks
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070
Facsimile: (858) 678-5099
Email: brooks@fr.com

ATTORNEYS FOR PLAINTIFF ALLERGAN, INC.

By: */s/ Walter J. Kawula*

Walter J. Kawula
Robert B. Breisblatt
A. Sidney Katz
James White
Sherry Rollo
WELSH & KATZ, LTD.
120 South Riverside Plaza, 22nd Floor
Chicago, IL 60606
Telephone: (312) 655-1500
Facsimile: (312) 655-1501
Email: wjkawula@welshkatz.com
Email: rbbreisblatt@welshkatz.com
Email: askatz@welshkatz.com
Email: jpwhite@welshkatz.com
Email: srollo@welshkatz.com

Richard L. Horwitz
Kenneth L. Dorsney
POTTER ANDERSON & CORROON LLP
Hercules Plaza
1313 North Market Street, 6th Floor
P.O. Box 951
Wilmington, DE 19899
Telephone: (302) 984-6000
Facsimile: (302) 658-1192
Email: rhorwitz@potteranderson.com
Email: kdorsney@potteranderson.com

Attorneys for Defendants
APOTEX INC. AND APOTEX CORP.

By: */s/ Daniel G. Brown*

Daniel G. Brown
Arthur L. Hoag
Barry S. White
David A. Zwally
Brian J. Malkin
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, New York 10151
Telephone: (212) 588-0800
Facsimile: (212) 588-0500
Email: dbrown@flhlaw.com
Email: ahoag@flhlaw.com
Email: bwhite@flhlaw.com
Email: dzwally@flhlaw.com
Email: bmalkin@flhlaw.com

Frederick L. Cottrell, III
Kelly E. Farnan
RICHARDS, LAYTON & FINGER, P.A.
One Rodney Square
P.O. Box 551
Wilmington, DE 19899
Telephone: (302) 651-7700
Facsimile: (302) 651-7701
Email: cottrell@rlf.com
Email: farnan@rlf.com

Roderick G. Dorman
Mieke K. Malmberg
HENNIGAN BENNETT AND DORMAN
865 S. Figueroa Street, Suite 2900
Los Angeles, CA 90017
Telephone: (213) 694-1200
Facsimile: (213) 694-1234
Email: dormanr@hbdlawyers.com

Attorneys for Defendants EXELA PHARMSCI, INC., EXELA PHARMSCI PVT., LTD., PADDOCK LABORATORIES and PHARMAFORCE, INC.

Discovery Period

Event	Allergan	Delaware Defendants	California Defendants
Substantial Completion of Document Production			3/7/08
Close of Fact Discovery	10/01/2008	8/1/2008	6/20/08
Opening Expert Report by Party with Burden of Proof	10/03/2008	7/18/2008	7/18/08
Responsive Expert Report	10/24/2008	8/15/2008	8/15/08
Rebuttal Expert Report	11/14/2008	9/12/2008	9/12/08
Close of Expert Discovery	12/19/2008	10/24/2008	10/24/08
Joinder of Other Parties and Amend Pleadings	2/29/2008	2/29/2008	2/29/08

Claim Construction

Event	Allergan	Delaware Defendants	California Defendants
Markman Hearing	Subject to Court's availability Dates below assumes ~8/11/2008	Early June 2008, subject to Court's availability	Not necessary.
Plaintiff's claim chart	5/16/2008	3/28/2008	Not necessary.
Defendant's claim chart	5/30/2008	4/11/2008	Not necessary.
Meet and Confer to Narrow Claim Chart	6/18/2008	4/25/2008	Not necessary.
Final Joint Claim Chart	6/25/2008	5/2/2008	Not necessary.
Opening Markman Briefs	7/11/2008	5/9/2008	Not necessary.
Responsive Markman Briefs	7/25/2008	5/23/2008	Not necessary.

Dispositive Motions

Event	Allergan	Delaware Defendants	California Defendants
Deadline to File Letter Brief Indication Intent to file MSJ	11/7/2008	9/5/2008	Not necessary.
Responsive Letter Brief Regarding Filing of MSJ	11/14/2008	9/19/2008	Not necessary.
Reply Letter Brief Regarding Filing of MSJ	11/28/2008	9/26/2008	Not necessary.
Status Conference to Determine Whether MSJ's Will be Allowed	~12/10/2008	~10/10/2008	Not necessary.
Deadline to File Case Dispositive Motions if Allowed	30 days after Status Conference	30 days after Status Conference	Not necessary.